In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 08-792V
(To be published)

* *		
BRIAN LONG and KIMBERLY LONG, as parents and natural guardians, on behalf of their minor son, BCL,	*	
Petitioners,	*	Filed: February 9, 2015
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES	*	Vaccine Act Entitlement; Causation-in-fact; Influenza Vaccine/Aggravation of Autism
Respondent.	*	
* *		

Sheila Bjorklund, *Lommen Abdo Law Firm, Minneapolis, MN, for Petitioners.*
Justine Daigneault, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION

HASTINGS, *Special Master*

This is an action in which Petitioners, Brian and Kimberly Long, seek an award under the National Vaccine Injury Compensation Program (hereinafter "the Program[1]), on account of their son BCL's autism spectrum disorder ("ASD"), which they believe was significantly aggravated by his receipt of the influenza ("flu") vaccine. For the reasons set forth below, I conclude that Petitioners are not entitled to an award.

[1] The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2006 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2006 ed.). At this time, I may also refer to the Act of Congress that created the Program or the "Vaccine Act."

I

THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In other cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused, or significantly aggravated, the injury in question. *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination caused or aggravated the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing or aggravating the condition, and was a "but for" cause. *Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

The *Althen* court also provided additional discussion of the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from *medical literature* supporting petitioner's causation contention, so long as the petitioner supplies the *medical opinion* of an expert. (*Id*. at 1279-80.) The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." (*Id*. at 1280.)

Since *Althen*, the Federal Circuit has addressed the causation-in-fact standard in several additional rulings, which have affirmed the applicability of the *Althen* test, and afforded further instruction for resolving causation-in-fact issues. In *Capizzano v. HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), the court cautioned Program fact-finders against narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records, may in a particular case be sufficient to satisfy that second element of the *Althen* test. Both *Pafford v. HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), and *Walther v. HHS*, 485 F.3d 1146, 1150 (Fed. Cir. 2007), discussed the issue of which party bears the burden of ruling out potential non-vaccine causes. *DeBazan v. HHS*, 539 F.3d 1347 (Fed. Cir. 2008), concerned an issue of what evidence the special master may consider in deciding the initial question of whether the petitioner has met her causation burden. The issue of the temporal relationship between vaccination and the onset of an alleged injury was further discussed in *Locane v. HHS*, 685 F.3d 1375 (Fed. Cir. 2012), and *W.C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013). *Moberly v. HHS*, 592 F.3d 1315 (Fed. Cir. 2010), concluded that the "preponderance of the evidence" standard that applies to Vaccine Act cases is the same as the standard used in traditional tort cases, so that *conclusive* proof involving medical literature or epidemiology is *not* needed, but demonstration of causation must be more than "plausible" or "possible." Both *Andreu v. HHS*, 569 F.3d 1367 (Fed. Cir. 2009), and *Porter v. HHS*, 663 F.3d 1242 (Fed. Cir. 2011), considered when a determination concerning an expert's credibility may reasonably affect the outcome of a causation inquiry. *Broekelschen v. HHS*, 618 F.3d 1339 (Fed. Cir. 2010), found that it was appropriate for a special master to determine the reliability of a diagnosis before analyzing the likelihood of vaccine causation. *Lombardi v. HHS*, 656 F.3d 1343 (Fed. Cir. 2011), and *Hibbard v. HHS*, 698 F.3d 1355 (Fed. Cir. 2012), both again explored the importance of assessing the accuracy of the diagnosis that supports a claimant's theory of causation. *Doe 11* v. HHS, 601 F.3d 1349 (Fed. Cir. 2010) and *Deribeaux v. HHS*, 717 F.3d 1363 (Fed. Cir. 2013), both discuss the burden of proof necessary to establish that a "factor unrelated" to a vaccine may have caused the alleged injury.

Another important aspect of the causation-in-fact case law under the Program concerns the factors that a special master should consider in evaluating the reliability of expert testimony and other scientific evidence relating to causation issues. In *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579 (1993), the Supreme Court listed certain factors that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues. In *Terran v. HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit ruled that it is appropriate for special masters to utilize *Daubert*'s factors as a framework for evaluating the reliability of causation-in-fact theories presented in Program cases.

In this case, the Petitioners do not assert that the influenza vaccination of November 21, 2005, *initially caused* BCL's autism. Rather, they assert that the vaccination caused a *significant aggravation* of BCL's autism. According to *W.C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013), "the National Vaccine Injury Compensation Program***allows certain petitioners to be compensated upon showing, among other things, that a person 'sustained, or had *significantly aggravated*' a vaccine-related 'illness, disability, injury, or condition.'" *Id*. at 1355-56, *quoting* 42 U.S.C. § 300aa-11(c)(1)(C))(emphasis added.) In *Whitecotton v. HHS,* 81 F.3d 1099, 1103 (Fed. Cir. 1996), the U.S. Court of Appeals for the Federal Circuit stated that "the statutory requirements to make out a *prima facie* significant aggravation claim are analogous to those required to make out a *prima facie* initial onset claim." The Vaccine Act states that "[t]he term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain or illness accompanied by substantial deterioration of health." § 300aa-33(4).

The elements of an off-Table *significant aggravation* case are set forth in *Loving v. HHS*, 86 Fed. Cl. 135, 144 (2009). There, the court combined the test from *Althen*, above, which defines off-Table causation cases, with the test from *Whitecotton v. HHS*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), which concerns on-Table significant aggravation cases. The resultant test has six components, which are:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significant worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C. v. HHS*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (holding that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims").

II

BACKGROUND: THE OMNIBUS AUTISM PROCEEDING ("OAP")

This case is one of more than 5,400 cases filed under the Program in which petitioners alleged that conditions known as "autism" or "autism spectrum disorders" ("ASD") were caused by one or more vaccinations. A special proceeding known as the Omnibus Autism Proceeding ("OAP") was developed to manage these cases within the Office of Special Masters ("OSM"). A detailed history of the controversy regarding vaccines and autism, along with a history of the development of the OAP, was set forth in the six entitlement decisions issued by three special masters as "test cases" for two theories of causation litigated in the OAP (see cases cited below), and will only be summarized here.

A group called the Petitioners' Steering Committee ("PSC") was formed in 2002 by the many attorneys who represented Vaccine Act petitioners who raised autism-related claims. About 180 attorneys participated in the PSC. Their responsibility was to develop any available evidence indicating that vaccines could contribute to causing autism, and eventually present that evidence in a series of "test cases," exploring the issue of whether vaccines could cause autism, and, if so, in what circumstances. Ultimately, the PSC selected groups of attorneys to present evidence in two different sets of "test cases" during many weeks of trial in 2007 and 2008. In the six test cases, the PSC presented two separate theories concerning the causation of ASDs. The first theory alleged that the *measles* portion of the measles, mumps, rubella ("MMR") vaccine could cause ASDs. That theory was presented in three separate Program test cases during several weeks of trial in 2007. The second theory alleged that the mercury contained in *thimerosal-containing vaccines* could directly affect an infant's brain, thereby substantially contributing to the causation of ASD. That theory was presented in three additional test cases during several weeks of trial in 2008.

Decisions in each of the three test cases pertaining to the PSC's *first* theory rejected the petitioners' causation theories. *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd* 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).[2] Decisions in each of the three "test cases" pertaining to the PSC's *second* theory also rejected the petitioners' causation theories, and the petitioners in each of those three cases chose not to appeal. *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

The "test case" decisions were comprehensive, analyzing in detail all of the evidence presented on both sides. The three test case decisions concerning the PSC's *first* theory (concerning the MMR vaccine) totaled more than 600 pages of detailed analysis, and were

[2] The petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims.

solidly affirmed in many more pages of analysis in three different rulings by three different judges of the United States Court of Federal Claims, and in two rulings by two separate panels of the United States Court of Appeals for the Federal Circuit. The three special master decisions concerning the PSC's *second* theory (concerning vaccinations containing the preservative "thimerosal") were similarly comprehensive.

All told, the 11 lengthy written rulings by the special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit *unanimously rejected* the petitioners' claims, finding no persuasive evidence that either the MMR vaccine or thimerosal-containing vaccines could contribute in any way to the causation of autism.

Thus, the proceedings in the six "test cases" concluded in 2010. Thereafter, the Petitioners in this case, and the petitioners in other cases within the OAP, were instructed to decide how to proceed with their own claims. The vast majority of those autism petitioners elected either to withdraw their claims or, more commonly, to request that the special master presiding over their case decide their case on the written record, uniformly resulting in a decision rejecting the petitioner's claim for lack of support. However, a small minority of the autism petitioners have elected to continue to pursue their cases, seeking other causation theories and/or other expert witnesses. A few such cases have gone to trial before a special master, and in the cases of this type decided thus far, all have resulted in rejection of petitioners' claims that vaccines played a role in causing their child's autism. *See*, *e.g.*, *Blake v. HHS*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. Vowell May 21, 2014) (autism not caused by MMR vaccination); *Henderson v. HHS*, No. 09-616V, 2012 WL 5194060 (Fed. Cl. Spec. Mstr. Vowell Sept. 28, 2012) (autism not caused by pneumococcal vaccination); *Franklin v. HHS*, No. 99-855V, 2013 WL 3755954 (Fed. Cl. Spec. Mstr. Hastings May 16, 2013) (MMR and other vaccines found not to contribute to autism); *Coombs v. HHS*, No. 08-818V, 2014 WL 1677584 (Fed. Cl. Spec. Mstr. Hastings Apr. 8, 2014) (autism not caused by MMR or Varivax vaccines). In addition, some causation autism claims have been rejected without trial, at times over the petitioner's objection, in light of the failure of the petitioner to file plausible proof of vaccine-causation. *See, e.g., Waddell v. HHS*, No. 10-316V, 2012 WL 4829291 (Fed. Cl. Spec. Mstr. Campbell-Smith Sept. 19, 2012) (autism not caused by MMR vaccination); *Geppert v. HHS*, No. 00-286V, 2012 WL 2500852 (Fed. Cl. Spec. Mstr. Vowell Sept. 6, 2012); *Fesanco v. HHS*, No. 02-1770, 2010 WL 4955721 (Fed. Cl. Spec. Mstr. Hastings Nov. 9, 2010); *Fresco v. HHS*, No. 06-469V, 2013 WL 364723 (Fed. Cl. Spec. Mstr. Vowell Jan. 7, 2013); *Pietrucha v. HHS*, No. 00-269V, 2014 WL 4338058 (Fed. Cl. Spec. Mstr. Hastings Aug. 22, 2014). Judges of this court have affirmed the practice of dismissal without trial in such a case. *E.g.*, *Fesanco v. HHS*, 2011 WL 1891701 (May 16, 2011) (Judge Braden).

In none of the rulings since the test cases has a special master or judge found any merit in an allegation that any vaccine can contribute to causing autism.

III

PROCEDURAL HISTORY OF THIS CASE

On November 4, 2008, Brian and Kimberly Long ("Petitioners") filed a "Petition for Vaccine Compensation" on behalf of their son, BCL. Petitioners at that time alleged generally that the "recommended childhood vaccinations" caused BCL "to develop pervasive developmental disorder-not otherwise specified ("PDD-NOS") and/or an autism spectrum disorder ("ASD")." (Petition ("Pet") at 1.)

In their petition, Petitioners further claimed that BCL suffered the *significant aggravation* of his "pre-existing vaccine injury" by an influenza vaccine administered on November 21, 2005. (*Id.*) Finally, Petitioners stated that they seek compensation not for the alleged initial injury by unspecified vaccinations, but for the *significant aggravation* allegedly caused by the 2005 flu vaccination. (*Id.*) At the same time that the petition was filed, Petitioners filed Exhibits 1-20, which are the medical records of BCL.

This case was originally assigned to Special Master Golkiewicz. (Notice, ECF No. 2.) Additional medical records, medical articles, and other documents were filed by Petitioners at various times thereafter, as Petitioners' Exhibits 21 through 41. Respondent has also filed Exhibits at various times, identified as Ex. A through Ex. G.

On February 5, 2009, Respondent filed a "Rule 4(c) Report" urging that compensation be denied. (ECF No. 7.) On May 24, 2011, the case was reassigned to my docket. Petitioners eventually filed two expert reports by Dr. Mary Megson, a pediatrician, on October 7, 2011 (Ex. 24), and November 13, 2012 (Ex. 24-1), supporting their causation allegation.

Respondent filed an expert report of Dr. Bennett L. Leventhal, a child psychiatrist (Ex. A), on July 16, 2012, and an expert report of Dr. Stephen Cederbaum, a geneticist, on March 18, 2013 (Ex. C). Both parties also filed certain medical literature.

On September 25, 2013, a "fact hearing" took place in Richmond, Virginia, at which I heard testimony from the Long family. (*See* Transcript of Proceedings "(1-Tr.)", ECF No. 40.) On February 10, 2014, I conducted a second hearing, to hear the expert testimony of Drs. Megson, Leventhal, and Cederbaum. (*See* Transcript of Proceedings "2-Tr.", ECF No. 51.) On March 25, 2014, Petitioners' counsel filed their post-hearing brief. On June 6, 2014, Respondent's counsel filed a responsive post-hearing brief. (Petitioners had the opportunity to file a reply brief, but have not done so.)

IV

FACTUAL HISTORY

BCL was born on September 7, 1998. (Ex. 1, p. 1.) As a baby, BCL suffered from "severe colic" and was therefore fed several different formulas. (Ex. 16, p. 23; Ex. 20, p. 30.)

BCL's first "sick visit" to his pediatrician occurred on January 28, 1999, when he was treated for an upper respiratory infection and otitis media. (Ex. 5, p. 20.) During his early childhood, BCL was treated for several other episodes of otitis media. Further, BCL contracted croup and bronchitis in February, 2003. (*Id.,* pp. 60, 62.)

Throughout the course of his early pediatric care, BCL received numerous routine pediatric vaccinations. Some of BCL's early medical records indicate concern about BCL's development. For example, pediatric records dated January 11, 2002, indicate concerns about BCL's unclear and delayed speech. (Ex. 5, pp. 38-39.) At a speech evaluation on May 6, 2002, he found to have a "moderately severe articulation disorder," and weekly therapy was recommended. (*Id.,* p. 50.) Although records dated August 9, 2002, note that BCL was "making progress [with] speech," by February 2003, his mother thought that the therapy was not helping, and that "something else is going on." (*Id.,* pp. 52, 61.)

On February 17, 2003, BCL was referred for further evaluation because of "Sensory irregularities," including "difficulty [with] fine motor language . . . . Is very easily distracted." (Ex. 5, p. 63.) BCL underwent an occupational therapy evaluation on March 3, 2003. (Ex. 8, pp. 2-5.) The report notes that BCL "does socially interact with children his own age and adults; however, frequently prefers to be by himself playing." (*Id.,* p. 2.)

Notes from BCL's pediatrician indicated a desire for BCL to undergo testing for Attention Deficit Disorder ("ADD"). (Ex. 5, pp. 85-86.) Accordingly, BCL was assessed by Larry Raskin, Ph.D., in late March to early April, 2003. (Ex. 6, pp. 15-17.) Dr. Raskin concluded that BCL had probable Attention Deficit-Hyperactivity Disorder ("ADHD"), and recommended medication. (*Id.,* p. 15.) Over the course of the next year, BCL was treated with various doses of several medications, including Ritalin, Adderall XR, Concerta, and Strattera. (Ex. 5, pp. 91, 96-97, 110-11, 179.)

On March 9, 2004, BCL visited Louisville Neurology Associates. (Ex. 5, p. 159.) The examining physician, Dr. Puri, concluded that BCL's "findings are suggestive of mild PDD or an autistic spectrum disorder possibly" (*id.*), and that BCL be evaluated for the same at the Child Evaluation Center (*id*., p. 160).

On June 14, 2004, BCL underwent occupational therapy, speech and language, psychological, and comprehensive medical evaluations at the Weisskopf Child Evaluation Center. (Ex. 5, pp. 182-93.) The experts indicate that BCL had made progress in some areas, but still had various difficulties, including attention problems and impulse control. (*Id.*) His full-scale IQ score, at 60, was within the deficient range. (Ex. 5, pp. 189-90.)

A brain MRI conducted on September 8, 2004, revealed "mild prominence of the cerebral sulci," but was otherwise normal. (Ex. 5, p. 209.) A medication management evaluation on April 12, 2005, noted that BCL was making great progress and doing well in his kindergarten class at Summit Academy. (*Id.,* p. 234.) A year-end report from BCL's teacher also lauded his progress during the 2004-05 school year. (Ex. 7, p. 4.)

BCL's family moved from Louisville, Kentucky, to Beaumont, Texas, during the summer of 2005. (Ex. 12, p. 21.) That fall, BCL enrolled in St. Anne Catholic School. (*Id.,* p. 3.)

According to his mother, BCL "had trouble adjusting at first" at the new school, but started to do better until the family was evacuated for three weeks due to a hurricane, after which "things progressively became worse." (*Id.,* p. 21.) A note from the office of Rosa Gonzalez, M.D., dated November 10, 2005, indicated that BCL's teachers said that his behavior was "not like him. Getting up—running out of classroom. Not paying attention." (Ex. 10, p. 11.)

On November 21, 2005, BCL received an influenza vaccine. (Ex. 18, p. 2.) BCL's pediatric records from this time do not indicate any adverse reaction to this vaccination. (Ex. 10, pp. 14-17.)

Throughout the rest of the 2005-2006 school year, BCL continued to have problems and poor school performance. His medications were frequently altered. (Ex. 10, pp. 17-18, 20-21, 26, 39.) Notes from March 30, 2006, indicate that BCL was having "mild hallucinations" and exhibiting high anxiety. (*Id.* at p. 29.) A special education form filled out by BCL's mother on May 17, 2006, stated that she attributed his problems in school to "[A]nxiety depression and dealing with new environment and a lot of changes." (Ex. 12, pp. 20-21.) On July 27, 2006, BCL was evaluated at Texas Children's Hospital. (Ex. 13, p. 19.) It was noted that BCL was diagnosed with developmental delay and sensory integration issues at four years of age, but that he had "regression in the last 6-9 months." (*Id.*) The evaluating pediatric neurologist commented that "it is possible" that this regression "is a normal manifestation of his pervasive developmental disorder." (*Id.*, p. 21.)

BCL visited Texas Children's Hospital on September 5, 2006, for a new patient neurology evaluation. (Ex. 13, p. 19.) Records from this evaluation indicate that BCL's "parents have noted marked changes in the last few months, which are: decreased memory, decreased socialization with them and others, decreased need for sleep, increased aggressiveness, more frequent outbursts, increased hyperreactivity, and bladder control problems." (*Id.*) Furthermore, the record indicates that BCL's parents first began to notice problems several months after their move to Texas. (*Id.*)

BCL was treated at the Lawlis-Peavey PsychoNeuroPlasticity Center beginning in March 2007. (Ex. 17, p. 5.) Records indicate that BCL's parents stated that he began to regress in March 2006. (*Id.,* p. 26.) However, an arrow points from this statement to a handwritten note that reads, "Regression started in November or December of 2005." (*Id.*)

The record of this case indicates that since 2007, BCL has experienced periods of improvement mixed with periods of worsening. Now age 16, BCL, unfortunately, continues to suffer from autism and "intellectual disability" (formerly known as "mentally retarded"), experiencing severe defects in many areas of development.

V

SUMMARY OF EXPERT WITNESSES' QUALIFICATIONS AND OPINIONS

In this case, Petitioners presented the expert report and testimony of one medical expert; Respondent presented the expert report and testimony of two medical experts. At this point, I will briefly summarize both the qualifications and the opinions of these expert witnesses.

A. Petitioners' expert, Dr. Mary Megson

1. Qualifications

Dr. Mary Megson, M.D., graduated *cum laude* in 1974 from Hollins College with a Bachelor in Science, and was designated as Phi Beta Kappa. (Ex. 41, p. 1.) She earned her M.D. from The University of Virginia School of Medicine in 1978. (*Id.*) She interned and completed her residency at the Boston Floating Hospital at Tufts Medical Center. (*Id.*) She continued to complete a fellowship in Ambulatory Pediatrics at Boston Children's Hospital, as well as a fellowship in Child Development at the Medical College of Virginia. (*Id*.)

Dr. Megson is certified by the American Board of Pediatrics. (*Id.)* Currently, she is in private practice, and acts as CEO of the Pediatric and Adolescent Ability Center, where she specializes in the treatment of autistic individuals. (*Id.,* 2-Tr. 175-77.) She has treated thousands of autistic patients (2-Tr. 177), and currently about 85 to 92 % of her patients are autistic (2-Tr. 175).

2. Summary of Dr. Megson's opinion

Summarizing Dr. Megson's opinion in this case is not an easy task, she since often stated her points vaguely or unclearly. However, by studying both her two written expert reports[3] and her hearing testimony it would be fair to summarize her opinion as follows.

Dr. Megson acknowledges that BCL had some neurologic abnormalities prior to his influenza vaccination of November 21, 2005. She acknowledges that he had ADHD. (*E.g.,* Ex. 24, p. 1.) At times in her presentation she also acknowledged that BCL, prior to November 21, 2005, also had "previously-diagnosed PDD-NOS," which is a form of autism spectrum disorder. (Ex. 24, p. 1.)

Dr. Megson opined, however, that the flu vaccination significantly aggravated BCL's pre-existing neurologic problems, including his autism, making them far worse. (Ex. 24, p. 1; Ex. 24-1, p. 1.)

Her theory of *how* the vaccination allegedly aggravated BCL's disorder, as best I can understand it, is as follows. Dr. Megson started with the fact that genetic testing has shown that BCL has a variant or "mutation" of the MTHFR gene, in the C677T allele of that gene. (Ex. 24, p. 6; Ex. 24-1, p. 2; 2-Tr. 215-216.) She opined that this genetic variant can disturb "the metabolic pathways regulating oxidative stress in the brain" (Ex. 24, p. 6; 2-Tr. 218), and that

[3] As noted above, Petitioners filed an expert report of Dr. Megson, identified as Ex. 24 on Oct. 7, 2011, on a compact disc. On Nov. 13, 2012, Petitioners filed a *supplemental* expert report of Dr. Megson, electronically identified as Ex. 24-1.

excessive oxidative stress can disturb brain function, thus aggravating autism (Ex. 24-1, pp. 2-3; 2-Tr. 288).

Dr. Megson further opined that BCL's flu vaccination, on November 21, 2005, by exposing BCL to 25 micrograms ("mcg") of mercury contained as a preservative (known as thimerosal) in that vaccination, caused considerable damage to BCL's brain, because he was particularly susceptible to such damage because of his MTHFR genetic variant. (Ex. 24, pp. 7, 9; 2-Tr. 229.)

Dr. Megson also relied on evidence that BCL's autism symptoms took a major turn for the worse in the period of several months after the flu vaccination in question. (*E.g.*, Ex. 24, pp. 4-5; 2-Tr. 201-10; 254-57.)

B. Respondent's experts

1. Dr. Cederbaum's qualifications

Dr. Stephen Cederbaum, M.D., attended Amherst College and graduated *cum laude* in 1959, with an A.B. Honors in Chemistry. (Ex. D, p. 1.) Dr. Cederbaum additionally graduated in 1964 from New York University with an M.D. Honors in Biochemistry. (*Id.*) Dr. Cederbaum interned and did his residency at the Barnes Hospital in St. Louis, Missouri, from July 1964 to June of 1966. (*Id.*)

Dr. Cederbaum is licensed by the American Board of Medical Examiners, the state of California, and the American Board of Medical Genetics. (Ex. D, p. 2.)

From 1970 to 2010, Dr. Cederbaum served at the University of California, Los Angeles, as an Assistant Professor, Associate Professor, or Professor, of Psychiatry, Pediatrics, or Human Genetics. (Ex. D, p. 1.) From 1994 to 2003, he was Chief of the Division of Genetics, Department of Pediatrics, at that institution. (*Id.*) Since 2010 he has served at that same institution as a "Professor Emeritus--Recalled." Dr. Cederbaum has published about 150 peer-reviewed publications, plus 70 to 80 non-peer-reviewed publications. (2-Tr. 305.)

2. Summary of Dr. Cederbaum's opinion

Testifying in the area of his medical specialty, Dr. Cederbaum disagreed with Dr. Megson. Most importantly, Dr. Cederbaum disagreed strongly with Dr. Megson's assertion concerning the significance of the fact that BCL has a single C677T variant of his MTFHR gene. Dr. Cederbaum explained that, in fact, 35 to 40 percent of the entire population has that exact same variant. (Ex. C, p. 3; 2-Tr. 309, 314.) Dr. Cederbaum opined that the existence of such variant in a person would *not* make that person more susceptible to neurologic disorder or to *any* disorder or disease. (2-Tr. 318, 349; Ex. C, pp. 3-4.) Dr. Cederbaum noted that the C677T variant of the MTFHR gene has been studied intensively (2-Tr. 314), and that the strong medical consensus in the genetics specialty is that such variant is *not* associated with an increased rate for any disease or disorder. (2-Tr. 330, 338-39, 342-43, 363; Ex. C, p. 4; Ex. E.)

Dr. Cederbaum opined that BCL's autism was not influenced by the flu vaccine. (Ex. C, p. 6.)

3. Dr. Leventhal's qualifications

Dr. Bennett L. Leventhal, M.D., received a Bachelor of Science degree from Louisiana State University in 1972. (Ex. B, p. 1, ECF No. 19.) Dr. Leventhal graduated from Louisiana State University in 1974 with a degree in medicine. (*Id.*) Dr. Leventhal served as a resident in Psychiatry at Duke University Medical Center from 1974-1978. (*Id.,* p. 2.) He additionally served as a Fellow in the Child and Adolescent Psychiatry Duke University Medical Center. (*Id.*)

Dr. Leventhal is board-certified in both general psychiatry and adolescent psychiatry (2-Tr. 372.) He has specialized in adolescent psychiatry (autism is considered a psychiatric as well as a neurologic diagnosis). (2-Tr. 372, 374-75, 378-80, 482-83.) At the University of Chicago, he served for 25 years as Director of Child and Adolescent Psychiatry, and for 10 years as Chief of the Department of Psychiatry. (2-Tr. 372-73.) During his 40-year medical career, Dr. Leventhal has treated many autistic children, and his practice is largely focused on autism. (2-Tr. 374-75, 378-80, 433-36.) He has taught and lectured about autism around the world. (2-Tr. 374, 376-78.) Dr. Leventhal has participated in devising the medical tests for diagnosing autism (2-Tr. 374-75), and he frequently diagnoses autism in his clinical practice (2-Tr. 380). Dr. Leventhal has 152 peer-reviewed publications listed on his *curriculum vitae*, many of them pertaining to autism. (Ex. B, pp. 13-28; 2-Tr. 382.)

4. Summary of Dr. Leventhal's opinion

Dr. Leventhal, Respondent's expert in diagnosing and treating autism, testified that he found no merit in the second part of Dr. Megson's theory, that an influenza vaccination *can* aggravate a neurological disorder, and that it *did* significantly aggravate BCL's disorder. (Ex. A, pp. 16-18; 2-Tr. 387.)

While Dr. Megson suggested that BCL had only minimal neurological problems prior to his influenza vaccination on November 21, 2005, Dr. Leventhal studied BCL's medical records and concluded that BCL clearly was *significantly* delayed prior to that vaccination. (Ex. A, pp. 14-15; 2-Tr. 392-413.) Dr. Leventhal opined that by the time BCL was five years old, in 2003, he met the diagnostic criteria for autism, and also was clearly within the category of "intellectually disabled" (formerly known as "mentally retarded"). (Ex. A, p. 15.) This was still true when BCL received the flu vaccination at seven years of age. (*Id*.)

Dr. Leventhal acknowledged that the 2005-2006 school year went poorly for BCL, with deterioration of his behavior both at school and at home. (Ex. A, p. 16.) But Dr. Leventhal disagreed that the influenza vaccination had any adverse effect upon BCL. (Ex. A, p. 17; 2-Tr. 387.) Dr. Leventhal noted that in 2005 BCL experienced situations that could have explained the worsening of his behavior and school achievement--specifically a move of his family to a new

city, a new school, and a three-week evacuation because of a hurricane. (Ex. A, p. 16; 2-Tr. 414-15, 495-96.)

Further, he noted that with ASD it is common for behavior and developmental progress to wax and wane--*i.e.*, get better or worse--at various times, without any apparent reason. (2-Tr. 408, 422, 486.) He pointed out that the age of six or seven years, when a child is expected to face significant new challenges in school, is a *very common* time at which a child with autism takes a turn for the worse, in the ordinary course of autism. (2-Tr. 422, 486-88.) (BCL turned seven as the 2005-2006 school year began.)

Finally, Dr. Leventhal testified that there is no plausible evidence that an influenza vaccine, or any other vaccine, *could* aggravate autism, or *did* so in BCL. (Ex. A, p. 17; 2-Tr. 388.)

VI

SUMMARY OF MY OPINION

The shortest summary of my opinion is that I found Petitioners' expert Dr. Megson to be a very weak and unconvincing witness, while I found Respondent's experts to be far more qualified and far more persuasive.

In the first part of her theory, Dr. Megson based her reasoning on her view that a certain variant in BCL's genone made him substantially more susceptible to neurologic injury than the average person. However, Dr. Cederbaum, a geneticist, is far better qualified to testify concerning this issue than Dr. Megson, a pediatrician. His testimony, that such variant is *not* harmful, was far more persuasive on this point.

Second, Dr. Megson testified that BCL's influenza vaccination of November 21, 2005, caused him to go from a mild neurologic disorder, including a form of autism that is not severe, to a severe and debilitating form of autism. However, Dr. Megson never made a plausible case that the influenza vaccine *can* aggravate or otherwise affect a person's autism. Further, Dr. Leventhal, as a child psychiatrist, has far better medical qualifications concerning the subject of autism than does Dr. Megson, and Dr. Leventhal testified persuasively that there is no reason to think that the influenza vaccine *can* aggravate autism, or that it *did* aggravate BCL's autism in this case.

Accordingly, Petitioners have wholly failed to demonstrate that it is "more probable than not" that BCL's flu vaccination of November 21, 2005, aggravated his autism.[4]

[4] Petitioners have the burden of demonstrating the facts necessary to show entitlement to an award by a "preponderance of the evidence." § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970)(Harlan, J., concurring).

VII

I FOUND NO MERIT IN THE *FIRST* PART OF DR. MEGSON'S THEORY, CONCERNING BCL's GENETIC VARIANT

First, I will analyze Dr. Megson's first principal point, her assertion that the fact that BCL has a single variant of the C677T allele of the MTHFR gene made him especially susceptible to neurological injury by a vaccination. I found that Dr. Cederbaum was far more persuasive than Dr. Megson concerning this point.

For one thing, concerning this point Dr. Cederbaum is *far* more qualified than Dr. Megson. As noted above, Dr. Megson is a pediatrician. She has made no claim to any special training in genetics. Dr. Cederbaum, in contrast, has spent much of a 50-year medical career specializing in human *genetics*. (Ex. D, p. 1; 2-Tr. 302-05.) From 1994 to 2003, he was Chief of the Division of Genetics, Department of Pediatrics, at the University of California at Los Angeles. (Ex. D, p. 1.) Clearly, on the issue of the potential effects of a *genetic* variant, Dr. Cederbaum is much more qualified than Dr. Megson.

Moreover, Dr. Cederbaum's testimony concerning this point was far more logical and convincing than that of Dr. Megson. Dr. Cederbaum explained that in fact *35 to 40 percent of the entire population* have that exact same genetic variant, without any apparent detrimental effects. (Ex. C, p. 3; Tr. 309, 314.) Dr. Cederbaum explained that the existence of this variant has been extensively studied (Tr. 314), and that experts in the area have concluded that the existence of such a variant does *not* make a person more susceptible to neurologic disorder, or to any other disorder or disease. (2-Tr. 318, 330, 338-39, 342-43, 349, 363, 365; Ex. C, p. 4.) Dr. Cederbaum added that if Dr. Megson were correct that a single C677T variant made a person susceptible to neurologic disorder, then we would be practically prevented from vaccinating 35 to 40% of the entire population. (2-Tr. 361.)

In this regard, both parties submitted medical literature. Dr. Cederbaum relied on Ex. E, which, he asserted, demonstrated that experts in the specialty of genetics have reached a *strong consensus* that the C677T variant is *not* associated with increased risk of any disorder or disease. (2-Tr. 320, 338-39, 342-43, 362; Ex. C, p. 4, Ex. E.)

Dr. Megson also submitted certain medical literature related to this point, and testified briefly concerning that literature at the hearing. Dr. Cederbaum, on the other hand, presented testimony concerning the literature submitted by Dr. Megson (2-Tr. 325-331, 352-55), and concerning Ex. E that he submitted (2-Tr. 330, 338-39, 342-43, 363). I have reviewed this testimony of both experts concerning this literature, as well as the literature itself. I find that Dr. Cederbaum's discussion was much more persuasive. Ex. E, I find, provides strong support for Dr. Cederbaum's analysis, while Dr. Cederbaum's comments about the problems with the literature filed by Dr. Megson were also persuasive.

To be sure, Dr. Cederbaum clarified in his testimony that the presence of a single[5] C677T variant in the MTHFR, which BCL has, is not totally without meaning. He acknowledged that as a result of a single C677T variant, the methylation *capacity* of such a person would be only about 75% of that of a person without any such variant. (2-Tr. 320-21; Ex. C, p. 4.) But Dr. Cederbaum explains that this 25% reduction does *not* impair the person's methylation *function* at a clinically detectable or clinically significant level. (2-Tr. 313, 318, 365.) Dr. Cederbaum explained that each human has about 50 to 100 abnormalities in his or her genome, but in most cases when only one of two corresponding genes is abnormal, such an abnormality does *not* result in any clinically detectable function reduction. (2-Tr. 321, 324-25.) He explained that a single C677T variant in MTHFR would *not* reduce a person's methylation function at a clinically detectable or clinically significant level. (2-Tr. 313, 318, 322.)

In this regard, Dr. Megson testified that BCL's allegedly impaired methylation due to the C677T variant would result in reduced brain production of "glutathione," an important brain component. (*E.g.*, 2-Tr. 292.) But Dr. Cederbaum explained that there is no evidence that the C677T variant causes impaired production ("synthesis") of glutathione. (2-Tr. 321.)

Dr. Cederbaum testified that the C677T variant did *not* make BCL particularly susceptible to brain injury. (2-Tr. 308). He also found that there is no evidence for Dr. Megson's theory that the flu vaccine, acting *in concert* with a single C677T variant, caused any harm to BCL. (2-Tr. 323.)

Again, I find that the discussion in Ex. E strongly supports Dr. Cederbaum's testimony concerning these points.

In short, I find that Dr. Cederbaum's testimony, concerning this first part of Dr. Megson's theory, combined with Ex. E, was much more persuasive than Dr. Megson's presentation concerning this point. I find that Dr. Megson has wholly *failed* to establish the first part of her theory.

VIII

I FOUND NO MERIT IN THE *SECOND* PART OF DR. MEGSON's THEORY, CONCERNING THE ALLEGED AGGRAVATION OF AUTISM

Since I have rejected the *first* part of Dr. Megson's theory, as described in Section VII of this Decision above, I could end my analysis here, since rejection of her first part plainly dooms her overall causation theory. However, in the interest of completeness, I will also discuss why I reject the *second* part of Dr. Megson's theory, that the influenza vaccine damaged BCL's brain, thereby allegedly changing him from a child with mild neurologic problems to a child with a

[5] In general, humans have in their genome two copies of every gene. (2-Tr. 312-13, 324.) In BCL's case, *one* of his two genes, not both, has the C677T variant. In one of her expert reports, Dr. Megson had stated that BCL had the variant in *both* genes (Ex. 24-1, p. 2), but at the hearing she acknowledged that her report had been mistaken in that regard, and that BCL has only a *single* C677T variant in an MTHFR gene (2-Tr. 291).

severe form of autism. This part of Dr. Megson's theory must also be rejected, for many reasons.

A. Relative qualifications of experts

First, the qualifications of Respondent's expert concerning autism spectrum disorders, Dr. Leventhal, are much superior to those of Dr. Megson in that subject matter area.

Dr. Megson is, to be sure, a board-certified pediatrician who, to her credit in this regard, has spent much of her 37-year medical career engaged in treating children with autism spectrum disorders.[6] (2-Tr. 175-77.) However, Dr. Leventhal has far superior *academic* credentials and *specialized medical training* qualifications in the area of *autism*. Autism is considered a psychiatric diagnosis as well as a neurological diagnosis. (*E.g.*, 2-Tr. 482-83.) Dr. Leventhal explained that child psychiatrists and pediatric neurologists are the most qualified experts to diagnose and treat autism. (2-Tr. 483.) Dr. Leventhal, board-certified in both general psychiatry and adolescent psychiatry (2-Tr. 372), has specialized in adolescent psychiatry (2-Tr. 372, 374-75, 378-80). At the University of Chicago, he served for 25 years as Director of Child and Adolescent Psychiatry, and for10 years as Chief of the Department of Psychiatry. (2-Tr. 372-73.) Moreover, during his 40-year medical career, Dr. Leventhal has specialized in autism, and has treated many autistic children. (2-Tr. 374-75, 378-80, 433-34.) He has taught and lectured about autism around the world. (2-Tr. 374, 376-78.) Dr. Leventhal has participated in devising the medical tests for diagnosing autism (2-Tr. 374-75), and he frequently diagnoses autism in his clinical practice (2-Tr. 280). Dr. Leventhal has 152 peer-viewed publications listed on his *curriculum vitae*, many of them pertaining to autism. (Ex. B, pp. 13-28.) He has received important awards for his work in autism. (2-Tr. 376.)

Thus, in terms of *specialized medical training* relevant to autism, Dr. Leventhal has the much superior resume.

B. Dr. Megson presented no plausible evidence that flu vaccine can cause or aggravate autism, and Dr. Leventhal was far more persuasive.

Second, Dr. Megson simply failed to present any *plausible evidence* that an influenza vaccine *can* aggravate autism or any neurological disorder, much less that it *did* aggravate BCL's neurological disorder. Dr. Megson spent the large majority of her testimony at the evidentiary hearing testifying concerning her belief that BCL's genetic variant allegedly made him *susceptible* to brain damage. (I have rejected that part of the theory in Section VII of this Decision above.) In contrast, she spent relatively little time attempting to explain how the *influenza vaccine* could damage a child's brain, thereby aggravating autism.

[6] Dr. Megson is *not* board-certified in the sub-specialties within pediatrics—*i.e.*, "developmental behavior pediatrics" or "neurodevelopmental disabilities"—that would be most relevant to autism spectrum disorder. (2-Tr. 262.) Dr. Megson usually treats individuals who have been diagnosed by *someone else* with ASD. (2-Tr. 178.) And if she sees a patient who has not been diagnosed, she often refers that patient to a specialist for a formal autism diagnosis. (*Id*.)

To be sure, Dr. Megson did assert in her expert reports that BCL's flu vaccination of November 21, 2005, exposed BCL to 25 micrograms ("mcg") of mercury, contained as a vaccine preservative known as "thimerosal," suggesting that such mercury caused "oxidative stress" to his brain, thereby aggravating his autism. (Ex. 24, pp. 6, 7, 9; Ex. 24-1, pp. 2, 3.) But at the evidentiary hearing she did not explain or elaborate in any significant detail on these assertions. In no part of her reports or testimony did she point to any significant *evidence* that the influenza vaccine can aggravate autism or otherwise damage the brain.

In this regard, while Dr. Megson's basic theory of the case was that the small amount of the mercury contained in the influenza vaccine caused "oxidative stress" sufficient to severely damage BCL's brain, she was forced on cross-examination to, in effect, admit how speculative her causation theory is. She admitted that she cannot quantify the amount of oxidative stress caused by a single flu vaccination. (2-Tr. 288.) She acknowledged that she can't say how much oxidative stress could cause a regression in a person's autism. (2-Tr. 289.) She admitted that there exists no data from the 2005-2006 period to measure the actual oxidative stress in BCL at that time. (2-Tr. 290). These admissions, in effect, show that Dr. Megson's theory amounts to *pure speculation*.

After attending Dr. Megson's testimony, I received the impression that she does truly *believe*, for whatever reason, that vaccinations and metals can cause or aggravate autism. When she found out that BCL received an influenza vaccination during the period of time in which he was having academic troubles and a downturn in his behavior, during the 2005-2006 school year, she seems to have automatically jumped to the conclusion that it was his *influenza vaccine* that caused his troubles during that school year by aggravating his autism.

I find Dr. Leventhal, on the other hand, to be quite persuasive in his testimony that there exists *no plausible evidence* that an influenza vaccine, or any other vaccine, *can* aggravate autism, or *did* so in BCL's case. (Ex. A, p. 17; 2-Tr. 388.) He opined, *inter alia*, that he has never seen any scientific proof that "oxidative stress" can affect autism. (2-Tr. 388.)

While Dr. Megson argued that BCL had only minimal neurological problems prior to his influenza vaccination on November 21, 2005, Dr. Leventhal studied BCL's medical records and concluded that BCL clearly was significantly delayed prior to that vaccination. (Ex. A, pp. 14-15; 2-Tr. 390-413.) Dr. Leventhal opined that by the time BCL was five years old, in 2003, he met the diagnostic criteria for autism, and also was clearly within the category of Intellectually Disabled (formerly known as Mentally Retarded). (Ex. A, p. 15.) This was still true when BCL received the flu vaccination at seven years of age. (Ex. A, p. 15.)

Dr. Leventhal acknowledged that the 2005-2006 school year went poorly for BCL, with deterioration of his behavior both at school and at home. (Ex. A, p. 16.) But Dr. Leventhal disagreed that the influenza vaccination had any adverse effect upon BCL. (Ex. A, p. 17; 2-Tr. 387.) Dr. Leventhal noted that in 2005 BCL experienced situations that could have explained the worsening of his behavior and school achievement--specifically a move of his family to a new city, a new school, and a three-week evacuation because of a hurricane. (Ex. A, p. 16; 2-Tr. 414-15, 495-96.)

Further, Dr. Leventhal explained that with ASD it is common for behavior and developmental progress to wax and wane--*i.e.*, get better or worse--at various times, without any apparent reason. (2-Tr. 388, 408, 422, 424-25, 486, 492; Ex. A, p. 15.) He pointed out that the age of six or seven years, when a child is expected to face significant new challenges in school, is a *very common* time at which a child with autism takes a turn for the worse, in the ordinary course of autism. (2-Tr. 413-14, 422, 486-88.) (BCL turned seven as the 2005-2006 school year began.) Thus, BCL's downturn in behavior in 2005-06 may be explained simply by the ordinary course of autism. (In this regard, note that one of BCL's *treating doctors* at the time wrote exactly that--that BCL's 2005-06 downturn "may be a normal manifestation of his pervasive developmental disorder"--Ex. 13, p. 2.)

C. Other individual points of Dr. Megson

Dr. Megson also added several additional observations about BCL's case, often in a disorganized fashion, in which it was impossible for me to tell how her different points fit within her basic "mercury/oxidative stress" theory. But, in any event, Dr. Leventhal effectively refuted Dr. Megson on many of these individual points. For example, Dr. Megson emphasized some still photographs of BCL before and after the flu vaccination in question, and argued that she could tell from these photos that there had been a significant worsening of his autism. (*E.g.*, 2-Tr. 245-46.) Dr. Leventhal, however, testified persuasively that still photos cannot tell us anything about the course of BCL's autism. (2-Tr. 430-31, 470-71, 481-82.)

Also, Dr. Megson, without significant elaboration, asserted that BCL's autism is a result of an ongoing *autoimmune response* by his immune system to the influenza vaccination. (2-Tr. 296-97.) Dr. Leventhal, however, testified that there was no evidence to support the contention that BCL has an "immunologic" brain defect. (2-Tr. 429.) He noted that in the case of such an immunologic cause for BCL's brain disorder, there would be chronic brain inflammation, for which a physician could easily test, but no such test has been done on BCL, and no evidence for brain inflammation in BCL exists. (2-Tr. 429-30.)

Third, Dr. Megson seemed somewhat ambiguous throughout her reports and testimony concerning whether BCL actually had an ASD prior to his flu vaccination of November 21, 2005. She clearly acknowledged that he had a neurological abnormality--ADHD, or Attention Deficit-Hyperactivity Disorder. At times she also acknowledged that he had an ASD prior to the vaccination. For example, in one report she wrote that he had a "previously diagnosed PDD-NOS"[7] prior to the vaccination. (Ex. 24, p. 1.) But at the evidentiary hearing, Dr. Megson at times seemed to assert that BCL did *not* have an actual ASD prior to the vaccination--for example, she testified that at age six years, seven months (April of 2005), BCL did *not* meet the criteria for an ASD. (2-Tr. 196.) Then, on cross-examination, she first admitted that he *did* have PDD-NOS prior to the vaccination (2-Tr. 273, line 10), then immediately back-tracked in her very next answer to say that BCL had only "features" of PDD-NOS, but not "full blown autism"

[7] There are five categories of ASD, including "PDD-NOS"--which stands for "Pervasive Developmental Disorder, Not Otherwise Specified." (2-Tr. 389.)

(2-Tr. 273, lines 13-16). She then seemed to acknowledge that BCL was on the autism spectrum at that time, but on the "mild end" of that spectrum. (2-Tr. 273, lines 17-19.)

Dr. Leventhal, on the other hand, indicated that while BCL was never adequately tested for ASD prior to the vaccination, based upon the medical records it appears retrospectively that he met the ASD criteria at age 5 and again at age 7 (the flu vaccination was administered at age 7 years and five months). (Ex. A, p. 15.) Further, Dr. Leventhal explained that he had never heard the term "full blown autism" before, and that PDD-NOS is *not* considered a mild form of autism. (2-Tr. 389.)

This exchange is not at all crucial to the outcome of this case, in which the overall evidence is overwhelmingly in Respondent's favor. But it simply again illustrates the often confusing and scattershot nature of Dr. Megson's testimony in this case.

D. It is common for no cause to be identified in autism.

In addition, Dr. Leventhal explained that is quite common in autism that, as in BCL's case, no definitive "cause" for the autism, or for changes in the autistic symptoms over time, is ever identified. (2-Tr. 429-30, 489, 490-91.)

E. Dr. Megson's reliance on timing

As part of their causation case, Petitioners and Dr. Megson also rely upon an assertion that BCL took a severe turn for the worse in his autism symptoms *immediately after* his influenza vaccination of November 21, 2005. They suggest that this alleged temporal relationship offers support to their claim of a causal relationship. There are several problems with this argument, however.

First as discussed at pp. 14-18 of this Decision, above, Dr. Megson was wholly unpersuasive in her arguments that the flu vaccine *can* aggravate autism or neurological disorders. Thus, even if petitioners were able to show a very stark temporal relationship between a sudden downturn in BCL's autism and his flu vaccination, the temporal relationship alone would *not* be enough to show that, more probably than not, the vaccination *caused* the downturn.

Moreover, a close examination of the entire record of this case demonstrates that Petitioners have *not* shown that BCL's autism symptoms took a sharp turn for the worse immediately *after* his vaccination, as they assert.

To be sure, as noted above, there is no doubt that during the 2005-2006 school year, BCL's behavior and his school performance deteriorated, as Dr. Leventhal did not dispute. But did this deterioration begin immediately or soon *after* the flu vaccination on November 21, 2005, as Petitioners now assert? An examination of the overall record makes this assertion seem doubtful.

In this regard, I acknowledge that during the *first* evidentiary hearing in his case, BCL's parents testified that the 2005-2006 deterioration began soon after the vaccination in question. (See Transcript, ECF No. 40.) I stress that I found BCL's parents to be very fine people, good parents, and admirably dedicated to BCL's welfare. But they were testifying in late 2013, about eight years after the events in question. Therefore, as to the *timing* of BCL's symptoms, I find that the *medical records* made at the time, or soon after, present a more reliable history of BCL's symptoms.

The medical records tell a different story than the scenario assumed by Dr. Megson. The records indicate that BCL's downturn during the 2005-06 school year began *prior* to his flu vaccination of November 21, 2005.

First, a note from the office of Rosa Gonzalez, M.D., dated November 10, 2005, *prior* to the vaccinations, indicates that BCL's teachers said that his behavior was "not like him. Getting up--running out of classroom. Not paying attention." (Ex. 10, p. 11.) And a second note in Dr. Gonzalez's records indicates that the new behaviors were persisting on November 15, 2005, again prior to the vaccination. (Ex. 10, p. 12.)

Second, in a questionnaire filled out by BCL's mother on May 17, 2006, she was specifically asked what she thinks caused BCL's recent difficulties. And she did *not mention the vaccination at all*; instead, she responded that the cause could be "dealing with new environment and a lot of changes." (Ex. 12, p. 21.) She added that "after the hurricane things got progressively worse." (*Id*.) (The hurricane occurred in September of 2005--*see* 1-Tr. 67-8.) Thus, apparently, in the mind of BCL's mother at that time, Mrs. Long was *not* remembering the downturn as starting right after any *vaccination*, but as starting after he experienced a "new environment and a lot of changes" (obviously, the family move and his entry into a new school), and after the hurricane evacuation, events which *predated* the vaccination.

Third, BCL's medical records do *not* show that BCL was taken to any physician soon after the November 21, 2005, vaccination with a complaint of sudden change of behavior. His pediatrician's notes do not show any visit in late November of 2005, and the notes of two visits in December of 2005 do not indicate any abrupt change of behavior (Ex. 10, pp. 16-17), but instead indicate only a "little bit of progress" (*id*. at 17).

In short, the medical records in this case actually *contradict* Dr. Megson's inference that BCL suffered a downturn soon *after* his influenza vaccination in question. They show that the beginning of his 2005-2006 downturn likely *predated* that vaccination.

F. Summary

In sum, for all the reasons stated above, I find no merit in the second part of Dr. Megson's theory, that an influenza vaccine *can* cause an *aggravation* of autism, or that it *did* cause an aggravation of BCL's autism.

IX

PETITIONERS' CASE FAILS THE TESTS REQUIRED BY *ALTHEN* AND *LOVING*

In this part of my Decision, I will explain how this case fits specially within the interpretive standards set forth in the *Althen* and *Loving* decisions. The short answer is that I find that Petitioners' case clearly does *not* satisfy the standards presented in either *Althen* or *Loving*.

The U.S. Court of Appeals for the Federal Circuit declared in *Althen* that it is a petitioner's burden:

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen, 418 F.3d at 1278 (citations omitted). There can be no doubt whatsoever that the *Althen* test ultimately requires that, as an overall matter, a petitioner must demonstrate that it is "more probable than not" that the particular vaccine was a substantial contributing factor in causing or aggravating the particular injury in question. That is clear from the statute itself, which states that the elements of a petitioner's case must be established by a "preponderance of the evidence." (§ 300aa-13(a)(1)(A).) The overall evidence here shows that the onset of BCL's autism occurred before the influenza vaccination in question, so it is clear that the influenza vaccine of November 21, 2005, was not the initial cause of his preexisting autism. However, in this case, Petitioners do not assert that the influenza vaccinations *initially caused* BCL's autism. Rather, the injury alleged is that the influenza vaccination of November 21, 2005, caused a *significant aggravation* of BCL's autism.

A. Analysis of a "significant aggravation" issue is guided by the ruling in Loving.

The Vaccine Act states that "[t]the term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain or illness accompanied by substantial deterioration of health." §300aa-33(4).

The elements of an off-Table significant aggravation case were set forth in *Loving v. HHS*, 86 Fed. Cl. 135, 144 (2009). The United States Court of Appeals for the Federal Circuit acknowledged that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims," in *W.C. v. HHS*, 704 F.3d 1352, 1357 (Fed. Cir. 2013). Thus, the Federal Circuit Court of Appeals, which sets binding precedent for decisions by the Office of Special Masters, endorsed the use of a six-part test for significant aggravation, which was first elaborated in *Loving*. A petitioner must prove by preponderant evidence that a vaccination caused significant aggravation by showing:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significant worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

W.C. v. HHS, 704 F.3d at 1357 (Fed. Cir. 2013).

The standard elaborated in *Loving*, and endorsed in *W.C. v. HHS*, combines elements from previous Federal Circuit decisions. *W.C. v. HHS*, 704 F.3d at 1537 ("The *Loving* test combines the first three *Whitecotton* factors, which establish significant aggravation, with the *Althen* factors, which establish causation.") Since the last three elements of the *Loving* test include the entirety of the *Althen* test, with insignificant wording modifications, the analysis of those three elements would be the same using either standard.

One interpretive issue with the *Althen* test concerns the relationship between the first two elements of that test (that is, prongs 4 and 5 of the *Loving* test). Initially, it was not absolutely clear how the two prongs differed from each other. That is, on their faces, each of the two prongs seems to require a demonstration of a "causal" connection between "the vaccination" and "the aggravation." However, a number of Program opinions concerning *Althen* have concluded that these first two elements reflect the analytical distinction that has been described as the "can cause" vs. "did cause" distinction. That is, in many Program opinions issued prior to *Althen* involving "causation-in-fact" issues, special masters or judges stated that a petitioner must demonstrate (1) that the *type* of vaccination in question *can* cause the *type* of injury in question, and also (2) that the particular vaccination received by the specific vaccinee *did* cause the *vaccinee's own* injury. *See*, *e.g.*, *Kuperus v. HHS*, 2003 WL 22912885, at *8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. HHS*, 2002 WL 31441212, at *18 n.42 (Fed. Cl. Spec. Mstr. Aug. 8, 2002). Thus, a number of judges and special masters of this court have concluded that Prong 1 of *Althen* is the "can cause" requirement, and Prong 2 of *Althen* is the "did cause" requirement. *See*, *e.g.*, *Doe 11 v. HHS*, 83 Fed. Cl. 157, 172-73 (2008); *Nussman v. HHS*, 83 Fed. Cl. 111, 117 (2008); *Banks v. HHS,* 2007 WL 2296047, at *24 (Fed. Cl. Spec. Mstr. July 20, 2007); *Zeller v. HHS*, 2008 WL 3845155, at *25 (Fed. Cl. Spec. Mstr. July 30, 2008).

Most importantly, the *Federal Circuit* confirmed that interpretation in *Pafford*, ruling explicitly that the "can it?/did it?" test, used by the special master in that case, was equivalent to the first two prongs of the *Althen* test. (*Pafford v. HHS,* 451 F.3d at 1352, 1355-56 (Fed. Cir. 2006).) Thus interpreting the first two prongs of *Althen* as specified in *Pafford*, under Prong 1 of *Althen* a petitioner must demonstrate that the *type* of vaccination in question can cause or aggravate the *type* of condition in question; and

under Prong 2 of *Althen*, that petitioner must then demonstrate that the *particular* vaccination did cause or aggravate the *particular* condition of the vaccinee in question. If these conclusions are applied to the analogous elements in the *Loving* test, then under Prong 4 of *Loving* a petitioner must demonstrate that the *type* of vaccination in question *can cause* the *type* of significant aggravation in question; while Prong 5 of *Loving* would require that the Petitioner also demonstrate that the particular vaccination *did cause* the *particular* aggravation in question.

B. Analysis of this case, under the six-part Loving/Althen test

In this Section, I will discuss whether Petitioners have satisfied the six-part *Loving* test to establish the existence of vaccine-related significant aggravation of a preexisting condition.

1. What was BCL's condition prior to the administration of the vaccine?

As explained above, all of the experts in this case agree that BCL was at least *somewhat* neurologically compromised *prior* to the influenza vaccination of November 21, 2005. Dr. Megson argued that his prior deficiency was minimal, while Dr. Leventhal more persuasively argued that BCL likely met the criteria for ASD, and also manifested significant intellectual disability.

2. What is BCL's current condition?

My conclusion, from studying the records of this case, is that BCL currently suffers from significant autism as well as significant intellectual disability.

3. BCL's current condition legally constitutes a "significant aggravation" of his prior condition.

My further conclusion is that BCL's current condition is, in fact, as Petitioners contend, significantly *worse* than his condition prior to the vaccination (though the worsening seems likely to have been the result of the normal course of autism, and was likely *not caused* by the vaccination). Therefore, under *Loving*, BCL's current condition likely *does* amount to a "significant aggravation" of his preexisting ASD.

4. Petitioners have failed to establish Prong 4 of Loving/Prong 1 of Althen.

As discussed above, Prongs 4, 5 and 6 of the *Loving* test are, in effect, the same as Prongs 1, 2, and 3 of the *Althen* standard. Under Prong 4 of *Loving*, and Prong 1 of *Althen*, a petitioner must provide a medical theory demonstrating that the *type* of vaccine in question can cause a significant worsening of the *type* of preexisting condition in question. In this case, however, the Petitioners have wholly *failed* to show that an influenza vaccination *can* aggravate a preexisting ASD, or any type of neurological disorder.

That is, as explained above, under Prong 4 of *Loving*/Prong 1 of *Althen* a petitioner must provide a medical theory demonstrating that the *type* of vaccine in question can aggravate the *type* of condition in question. Petitioners' theory is that BCL's influenza vaccine significantly aggravated BCL's previously diagnosed PDD-NOS and ADHD. However, in this case I have already explained in detail (see part VII of this Decision) how Dr. Cederbaum's testimony thoroughly refuted the *first* part of Dr. Megson's theory as to how a vaccine could cause or aggravate autism, and how Dr. Leventhal thoroughly refuted the *second* part of Dr. Megson's theory (see part VIII of this Decision). Accordingly, it is quite evident that Petitioners have wholly *failed* to establish Prong 4 of *Loving*/Prong 1 of *Althen* in this case.

5. Petitioners have failed to establish Prong 5 of Loving/Prong 2 of Althen in this case.

Under Prong 5 of *Loving*/Prong 2 of *Althen*, the Petitioners need to show that it is "more probable than not" that BCL's influenza vaccination *did* aggravate *BCL's* autism. But they have failed to do so, for all the reasons detailed above. As discussed in both Sections VII and VIII above, Dr. Megson's theory as to how the vaccination allegedly aggravated BCL's autism has been shown to be without scientific merit. Further, as shown in Section VIII, Dr. Megson's theory about BCL was based upon a mistaken assumption as to *when* his downturn began *within* the 2005-2006 school year.

6. Petitioners have failed to establish Prong 6 of Loving/Prong 3 of Althen in this case.

Since I have explained why Petitioners have failed to satisfy the *first* and *second* prongs of *Althen* (4th and 5th Prongs of *Loving*), I need not discuss why Petitioners' case also fails to satisfy the Prong 3 of *Althen*/Prong 6 of *Loving*. However, in the interest of completeness, I will note again that the medical records show that BCL's downturn during the 2005-2006 school year actually *predated* his flu vaccination (*see* pp. 19-20). Thus, Petitioners have also failed to establish Prong 6 of *Loving*/Prong 3 of *Althen* in this case.

C. This <u>not</u> a close case

As noted above, in *Althen*, the Federal Circuit indicated that the Vaccine Act involves "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280. Accordingly, I note here that this case is ultimately is *not* a close call. For all the reasons set forth above, I find that Dr. Megson's theory was *not at all* persuasive, while Respondent's experts were *far* more persuasive.[8]

[8] It should be noted that in this case the Petitioners never came close to carrying their burden of making a "*prima facie*" case showing that BCL suffered a vaccine-caused or vaccine-aggravated injury. Therefore, the burden *never shifted* to Respondent to demonstrate that BCL's condition was "due to factors unrelated to the administration of the vaccine." §300aa-13(a)(1)(B).

X

NOTATION CONCERNING VIABILITY OF DR. MEGSON AS AN EXPERT WITNESS IN FUTURE PROGRAM CASES

As I have stressed above, I found Dr. Megson, despite her apparent sincerity, to be a *very unpersuasive* witness in this case. Dr. Megson, in effect, relied on the theory that the miniscule amount of mercury in the thimerosal preservative in the influenza vaccine could cause or aggravate autism. (*E.g.*, Ex. 24, pp. 7, 9; Ex. 24-1, pp. 1, 3.) But that theory was thoroughly examined and soundly rejected by three special masters in the "second theory" autism test cases. *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

Further, Dr. Megson relied on the "oxidative stress" theory that was also soundly rejected in the same three test cases. (Ex. 24, p. 6, Ex. 24-1, pp. 2-3; 2-Tr. 288.) She acknowledged that in this regard she was specifically relying upon the work of Dr. Richard Deth, who testified in the second theory test cases, and whose analysis was rejected and criticized in those cases.[9] (Ex. 24-1, p. 2; 2-Tr. 236.)

Nor did Dr. Megson even seem to present her causation theories as any different than these previously-discredited theories, or offer any new evidence for these theories.

Therefore, I hereby put Vaccine Act attorneys (and *pro se* litigants) on notice that if Dr. Megson's opinion, relying on the same discredited theories devoid of any new and plausible evidence, is offered in future Vaccine Act cases, I will *not* be likely to compensate such petitioners for any work by Dr. Megson performed after the publication date of this Decision.

Further, I also stress to Vaccine Act attorneys and *pro se* litigants, as I have in the past, that it will likely be fruitless to present once again, even with different experts, the *same autism causation theories* that were rejected in the "test case" decisions and in the additional cases cited on Section II of this Decision above.

XI

CONCLUSION

The record of this case demonstrates plainly that BCL and his family have been through a tragic ordeal. I had the opportunity, in the courtroom during the first evidentiary hearing, to meet and observe BCL and his parents. I have also studied the records describing BCL's

[9] One discussion rejecting the "oxidative stress" theory in the autism "test case" rulings is set forth in *King v. HHS*, 2010 WL 892296 at *55-*61. For example, one highly qualified expert explained that the cumulative oxidative stress from a typical *six-month course* of childhood vaccines would cause no more oxidative stress than drinking a four-ounce glass of milk. 2010 WL 892296 at *56.

medical history, and the efforts of his family in caring for him. Based upon those experiences, the great dedication of BCL's family to his welfare is readily apparent to me.

Nor do I doubt that BCL's parents are sincere in their belief that BCL's vaccination played a role in aggravating BCL's autism. BCL's parents have heard the opinion of Dr. Megson, and perhaps other physicians, who profess to believe in a causal connection between vaccines and autism. After studying the extensive evidence in this case, I am convinced that the opinion provided by Petitioners' expert in this case, advising the Long family that there is a causal connection between the flu vaccination and an aggravation of BLC's autism, was *quite wrong*. Nevertheless, I can understand why BCL's parents found such opinion to be believable under the circumstances. I conclude that the Petitioners filed this petition in good faith.

Thus, I feel deep sympathy for the Long family. Further, I find it unfortunate that my ruling in this case means the Program will not be able to provide funds to assist this family, in caring for their child who suffers from a serious disorder. It is my view that our society does not provide enough assistance to families of *all* autistic children, regardless of the cause of their disorders. And it is certainly my hope that our society will find ways to ensure that in the future *much* more generous assistance is available to all such children. Such families must cope every day with tremendous challenges in caring for their autistic children, and all are deserving of sympathy and admiration. However, I must decide this case not on sentiment, but by analyzing the evidence. Congress designed the Program to compensate only the families of individual whose injuries or deaths can be linked causally, either by Table Injury or presumption or by preponderance of "causation-in-fact" evidence, to a listed vaccine. In this case, the evidence advanced by Petitioners has fallen far short of demonstrating such a link. Accordingly, I conclude that the Petitioners in this case are *not* entitled to a Program award on BCL's behalf.[10]

IT IS SO ORDERED.

/s/ George L. Hastings, Jr.
George L. Hastings, Jr.
Special Master

[10] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.